Comparison stage of vaginal delivery in painless labor with epidural & spinal analgesia

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Abstract

Aim: Aim of this study was comparison stage of vaginal delivery in painless labor with epidural &spinal analgesia. Material and Method: This study was clinical trials and double blind.90 pregnant women in Taleghani hospital entered in this study. We divided women in 3 groups (spinal analgesia, Epidural analgesia, control) randomly. We recorded Heart rate and blood pressure and oxygen saturation in mothers every 15 minutes and fetal heart rate and apgar in one and five minute after delivery and dilatation in cervix every 2 hours for full dilatation. Results: Mean of second stage in delivery in control group was less than others groups (p=0/01).In Epidural and spinal groups were not significant difference (P> 0/05). Discussion: Mean of second delivery in epidural and spinal analgesia decreased.

Keywords

Epidural; Spinal; Painless Labour; Vaginal Delivery Stage

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Introduction

Labor is a complicated mental experience. Various factors affect a women's perception of labor which makes any experience unique. However, the labor pain is classified as the most severe pains in the pain ranking scale compared to the other painful life experiences [1].

The labor pain is one of the most challenging experiences with which women face in their life. The painful labor causes physiological changes which may threaten the health of the mother and the baby [2]. Although the pain level experienced by a parturient depends on many factors such as the amount of using Oxytocin, dysfunctional labor, delivery phases duration, and even psychological issues, an ideal analgesia can be provided to relieve pain through different delivery phases such that it can satisfy the parturient needs [3]. Regarding the increased cesarean rate in Iran, the World Health Organization recommendation to decrease cesarean and increase normal delivery, and the new policies of population growth in the country, some plans were adopted to support normal delivery. Hence, the anesthesia specialists helped the gynecologists and midwives and presented different analgesia methods. Therefore, it is of the mothers' rights to have an analgesia delivery [2, 3, and 4]. The analgesic delivery should be secure and have the minimum unwanted consequences for the mother, baby, and the delivery procedure [4]. Neuraxial analgesia techniques are among the methods used in the today's modern world which seeks the high satisfaction level of the mothers and a desirable effectiveness; these techniques have been accepted as the most effective methods for pain relief with the minimal side effects and high quality in the last recent decades [3]. Different kinds of interventions have been carried out in the two last decades to achieve this goal; the interventions included using low doses of local anesthetics/ narcotic mixture, combined spinal and epidural anesthesia (CSE), patient-controlled epidural analgesia (PCEA), and spinal analgesia [5]. The modern neuraxial analgesia in the delivery procedure indicates a shift in the anesthesia field of Obstetrics and Gynecology since it changes the attitude from a simple concentration in the pain reduction to concentration in the overall quality of analgesia [6].

Nowadays, in many of the countries, the regional analgesia for delivery is considered as a reflection of the standard delivery cares [7]. About 60% of the women in the United States of America receive a kind of neuraxial analgesia. However, there is a concern regarding the negative impact of these methods on the delivery and delivery procedure [8]. Although the advantages of using these methods are known, there are controversies regarding their consequences [2]. The controversies indicate that these methods cause the increased cesarean rate, the increased need for forceps delivery, the increased delivery phases, and the increased need for Oxytocin. However, the prospective studies which have been recently done violate these results. In fact, one of the main reasons for the patients' refusal of neuraxial analgesia is its intervention with delivery phase and result [2]. In spite of these controversies, the rate of using these techniques is increasing. In Iran, these methods have been not completely used because of the concern regarding the analgesia impacts on the mother and the baby. Some studies have been conducted regarding pain control and pain reduction methods in the recent years. Some have indicated that the epidural anesthesia increases the whole delivery period and phases [9 and 10]. Moreover, some studies have indicated that the duration of the active phase is shortened [11 and 12]. Besides, some studies have also concluded that there is no significant difference between delivery and vaginal delivery in terms of duration [13 and 14]. Some papers have preferred the spinal method to the epidural one [15]. With regard to these disagreements, the researchers decided to conduct a study to compare the delivery phases in the two spinal and epidural methods.

Material and Method

This study is a randomized clinical trial which was double blindly conducted on all pregnant women visiting Arak Taleqani hospital; they were candidates for having a natural delivery. In this study, about 90 pregnant women who were candidates for having a natural delivery, had the inclusion criteria, and had the informed consent to participate in analgesic delivery were investigated as the population of the study. The nulligravida, primigravida, single birth, and 37-42 gestational age mothers had the inclusion criteria. They completed the informed consent form and were randomly divided into three equal groups using cubal Randomized: epidural analgesic delivery, analgesic delivery with spinal analgesia, and the control group which lacked any labor and pain. After doing hemodynamic recording, complete monitoring, fetal heart rate recording, the embryo health status assurance, and the mother's hemodynamic stability assurance, all patients went into normal vaginal delivery (NVD). In the first group, 30 pregnant mothers went under analgesia after a complete monitoring, taking the appropriate IV, and receiving the liquid (about 200-300 cc) in the seated stance by 4-6 cc of the 0.125 Marcaine in addition to 25 microgram Fentanyl that the desirable injection volume reached 10 ccs. It was done in an L4-L5 or L3-L4 space by the G20 epidural needle made by the German Bibrun company (in single shout). Then, the epidural catheter was fixed for the patients. The maintenance dose of the drug was about 6-10 cc of the 0.0002-percent Marcaine which was injected through the catheter. In the second group, 30 patients went under spinal analgesia in the seated stance, having the inclusion criteria, by the G25 needle made by the German Bibrun company in an L4-L5 or L5-S1 space, and with 50-75 microgram Fentanyl whose volume had reached to 2 ccs by distilled water. In the third group, 30 pregnant mothers had the inclusion criteria, were considered as the control group, and received no analgesic delivery method. Finally, the control-group mothers were put in a supine stance after doing the said blocks. Then, they were gone under normal vaginal delivery. The anesthesia technician monitored the mothers' vaginal delivery in the whole process and the vital signs including heart beats, the percentage of oxygen saturation, blood pressure, and also the fetal heart rate were recorded every 15 minutes. The intern partner for midwife precisely examined and recorded the delivery phases and times for cervical examinations per minute in terms of delivery progression in every 2 hours until full dilatation and delivery. Besides, in addition to the labor phase time, the mothers' vital signs, fetal heart rate, and Apgar were also recorded in the project questionnaires. The results of the aforementioned questionnaires were gone under statistical analysis

via SPSS 19. Finally, the data were presented as statistical tables and figures. The study was conducted in a double-blind procedure and this was confirmed since the intern partner was responsible for completing the project questionnaires and the person who was responsible for the project statistical analysis was completely unaware of the study procedure and the studied groups. The anesthesiologist prepared the drugs and gave to the resident who performed the analgesic labor (spinal and epidural analgesia). The project intern partner who was responsible for complete the questionnaires as well as the person who was responsible for doing statistical analysis were blind toward the studied groups. The pregnant mothers who were willing to participate in the project were completely randomly divided into spinal and epidural groups. The placebo group also included all mothers who were reluctant to go under analgesic labor (the mothers who were included in the project were also blind regarding the studied groups because the mothers who go under analgesic labor are separately treated in another room away from the mothers who would not experience analgesic labor).

-The Inclusion Criteria

1. All pregnant mothers who are in their 37-42 weeks of pregnancy.
2. Mothers whose completely informed consent to participate in the project has been confirmed.
3. All ASA mothers with class 1 and 2
4. The primigravida mothers
5. Single birth pregnancy
6. All mothers for whom the cervical dilation would be 3-4 centimeters at the beginning of the labor.
7. The lack of a systemic infection or fever and other ground diseases
8. Insensitivity to LA and narcotics
9. The absence of coagulopathy
10. Mothers with 18-40 years old

-The Exclusion Criteria

1. The lack of the informed consent for participating in the project
2. Class 2 and 3 of ASA
3. All patients for whom the epidural and spinal analgesia have been unsuccessful.
4. Patients sensitive to LA and narcotics
5. Mothers with a gestational age lower than 37 weeks
6. Mothers who are not primigravida.
7. Mothers with more than one fetus

A phase is randomly easy.

$$N = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (\delta_1 + \delta_2)^2}{(\mu_1 - \mu_2)^2} = 28$$

$$Z_{1-\frac{\alpha}{2}} = \frac{1}{96} \qquad \delta_1 = 12.2$$

$$\delta_2 = 104.37$$

$$Z_{1-\beta} = \frac{2}{33} \qquad \mu_1 = 7.5$$

$$\mu_2 = 68.4$$

To be more precise, 30 people are put in each group instead of 28 people. Therefore, n=90.

Results

Table 1. The Comparison of the Age Average among the Patients Candidate for delivery in the Three Groups of Epidural Analgesia, Spinal Analgesia, and the Non-analgesic Delivery Group

Age average Group	Epidural	Spinal	Non-analgesic delivery group	P-value
Age average ±SD	26.2 ±1.7	25.9 ±1.9	26.1 ±2.1	P ≥ 0.05

T-test

Regarding [table 1], there was not a significant difference among the three groups in terms of age and the age average of the three groups was nearly 26 years old (P ≥ 0.05).

Table 2. The Comparison of the Delivery Phases Mean among the Pregnant Women in the Three Groups of Epidural Analgesia, Spinal Analgesia, and the Non-analgesic Delivery Group

Groups	Epidural	Spinal	Non-analgesic delivery group	P-value
The first phase delivery mean (in hour)	5.7±1.7	5.4±1.3	5.9±1.9	≥ 0.05
The second phase mean (in terms of delivery minutes)	35.5±2.3	34.5±1.8	26.1±2.6	0.01

T-test

There was not a significant difference among the three groups of epidural analgesia, spinal analgesia, and the non-analgesic delivery group in terms of the first phase delivery means (P≥ 0.05). However, as [table 2] shows, there was a significant difference among the said three groups in terms of the second phase delivery mean. The second phase delivery mean was significantly lower in the non-analgesic delivery group compared to the other two groups (P=0.01). There was not a significant difference between epidural analgesia and spinal analgesia groups in terms of the second phase delivery (P≥ 0.05).

Table 3. The Comparison of the Babies' Apgar Means at 1 and 5 minutes in the Three Groups of Epidural Analgesia, Spinal Analgesia, and the Non-analgesic Delivery Group

Groups	Epidural	Spinal	Non-analgesic delivery group	P-value
The babies' Apgar means at 1minute	9.01±1.2	8.9±1.9	8.8±1.3	≥ 0.05
The babies' Apgar means at 5 minutes	9.8±1.8	9.8±1.6	9.7±1.1	≥ 0.05

T-test

As [table 3] indicates, there was not a significant difference among the three groups of epidural analgesia, spinal analgesia, and the non-analgesic delivery group in terms of the babies' Apgar means at 1 minute (P≥ 0.05). Besides, there was not a significant difference among the three groups in terms of the babies' Apgar means at 5 minutes (P≥ 0.05).

Table 4. The Comparison of the Pregnancy Weeks Means in the Patients Candidate for Delivery in the Three Groups of Epidural Analgesia, Spinal Analgesia, and the Non-analgesic Delivery Group

Age average Group	Epidural	Spinal	Non-analgesic delivery group	P-value
Age average ±SD	39.1 ±8.7	39.9 ±9.9	39.7 ±9.1	P ≥ 0.05

T-test

The gestational age means of the pregnant mothers in the three groups were almost equal and there was not a significant difference (P ≥ 0.05). Nearly, the gestational age means in the three groups was 39.8 weeks [table 4].

Table 5. The Comparison of the Side Effects Prevalence in the Mothers Candidate for Delivery in the Three Groups of Epidural Analgesia, Spinal Analgesia, and the Non-analgesic Delivery Group

Groups	Epidural	Spinal	Non-analgesic delivery group	P-value
Dizziness and headache	0	1	0	≥ 0.05
Backache	0	0	0	≥ 0.05
Nausea and vomiting	1	2	0	0.01

T-test

According to [table 5], there was not a significant difference in comparing the side effects of dizziness, headache, and backache in the three groups of epidural analgesia, spinal analgesia, and the non-analgesic delivery group (P ≥ 0.05). However, there was a significant difference between the three groups in terms of the side effects of nausea and vomiting such that nausea and vomiting were more in the spinal group than the other two groups (P=0.01).

Discussion

Achieving the difference between the delivery phase means in the various kinds of analgesic labor methods helps to optimally use these methods and more desirably control the labor pain. On the other hand, it is of importance to know the fact that whether using analgesic labor control methods leads to an increase in the delivery duration or not. It has been the major objective in the similar studies and can be a document for optimally using these methods. In the present study, the comparison of the delivery time means significantly showed that the second delivery phase duration means in the control group (the group which did not receive the analgesic delivery) was lower than the two groups of epidural and spinal. Besides, there was not a significant difference between the analgesic delivery groups (epidural and spinal) and the control group in the first delivery phase. In other words, using the analgesic delivery methods (epidural and spinal) not only does not increase the first delivery phase duration but also there is not a significant difference between this phase and the control group in terms of the delivery duration mean. The results of this study are nearly the same as and close to the ones obtained in the previous similar studies. Dr. Kamali, et al. (2016) conducted a study on comparing delivery phases in the analgesic delivery through the two methods of epidural analgesia and Entonox, indicating that the delivery phase duration mean (phases 1 and 2) in the two groups of epidural analgesia and Entonox was lower than that of the control group. Furthermore, in comparing the two groups of epidural analgesia and Entonox, it was shown that the delivery phase mean in the epidural group was higher than Entonox group [16]. A study was conducted in Qazvin, Iran (2002) and it was indicated that the epidural analgesic delivery shortens the delivery active phase while increases the second delivery phase compared to the normal delivery. Moreover, this study indicated that the caesarean prevalence in the two groups (epidural and control) was the same and they had similar baby Apgar [17]. The results of the abovementioned study were consistent with the present study because the second delivery phase mean of the epidural group was more than the control group in this study. Another study was conducted in India (2011-2014) on 120 nulligravida women and it was indicated that the first delivery phase duration in the epidural group was shorter than the control group, but the second delivery phase duration in the epidural group had increased compared to the control group. The rate of caesarean and delivery with aids had not increased in the epidural group and the Apgar at 5 minutes was similar in the two groups [18]. Another study was also done in Hamadan, Iran (2011) on 200 pregnant women and it was indicated that there is not a significant difference between the spinal and control group in terms of the first and second delivery phase duration. The results of this study were consistent with those of the present study, but the present study indicated that the second delivery phase in the analgesic delivery (epidural and spinal) had increased compared to the control group [14].

Lolaee and Teymouri (2011) conducted another study in Najmieh hospital, Tehran, and showed that there is not a significant difference between the different delivery phase times among the control, epidural, and spinal groups [19]. However, some of the available resources and studies have indicated that using regional analgesia in analgesic delivery prolongs the delivery procedure. The prospective study was carried out in Guangzhou, China (2011) by Zhang. It was indicated that the first phase, the second phase and the overall delivery duration in the epidural group had increased compared to the control group [20]. Undoubtedly, the normal delivery is severely painful; in McGill Pain Diagram (MCGILL) which was developed in 1990, it was made clear that after Causalgia (NEUROLEPTIC PAIN), the labor pain has a high score compared to other pains like fractures, cuts, and chronic backache. Therefore, it seems necessary to create a condition of comfort and analgesia during the labor so as to encourage the mothers to go under normal delivery and reduce the pregnant mothers' willingness to caesarean. The labor pain is one of the most important challenges a mother faces in her life. A painful delivery experience is the worst medical memory she would have in her life such that this experience causes the patients' severe fear of normal delivery and willingness to caesarean. During the painful physiologic delivery, a great amount of Epinephrine and Norepinephrine is released in the circulatory system in response to the mother's pain that causes various side effects including the increased mother's PR, excessive use of oxygen, and reduced blood supply to the fetus. Besides, the labor pain causes the pregnant mothers' hyperventilation, hypocapnia (reduced CO_2), acid-base disorders, and finally insufficient reception of oxygen by the baby. All the above items can be controlled and eliminated by an effective analgesic delivery.

Using the two methods of epidural analgesia and spinal analgesia is completely effective in controlling labor pain in the first and second delivery phases. As it is known, segments T_{10} to L_1 are responsible for innervating the dermatomes related to the first delivery phase and segments S_2 to S_4 are responsible for innervating the second delivery phase. The recent studies indicate that the two epidural and spinal methods are effective in controlling pain in the two delivery phases. The studies conducted by the present researchers indicated that the patients in the two epidural and spinal methods were equally satisfied. The special regional techniques by epidural analgesia are very effective and flexible and have little side effects. This study indicated that the epidural and spinal analgesic delivery do not have a significant effect on the babies' health and Apgar at the 1 and 5 minutes and the Apgar at 5 minutes was 10 in the three groups. Furthermore, there was not a great difference in the three control, epidural, and spinal groups in terms of caesarean prevalence. However, according to some studies, the caesarean prevalence in the mothers who had used the analgesic delivery methods was more than the control group. Regarding the side effects of the pain control methods during labor, hypotension and bradycardia were the only side effects which were observed in the analgesic delivery group and only happened at 15 to 20 percent of the basic level; however, there was no special side effect caused by the analgesic delivery methods in the said mothers. Regarding the previous studies and the results of this study, it can be said that using the analgesic delivery methods leads to the mothers' comfort and satisfaction during labor; this is an effectively important factor in reducing the mothers' willingness to go under caesarean and surgery. In fact, the pregnant mothers' satisfaction during labor is a very important factor which plays a significant role in reducing the rate of caesarean in different societies. In this study, the mothers' satisfaction in epidural and spinal groups was clearly more than the mothers in the control group and there was not a significant difference between the two epidural and spinal groups. Anyway, it seems necessary that conducting similar studies with more participants is an essential and inevitable issue so as to develop the epidural and spinal analgesic delivery so that the results of this study can be generalized to other societies.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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